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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,061	07/31/2003	Robert E. Richard	02-321	9972

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EXAMINER	
SIMMONS, CHRIS E	
ART UNIT	PAPER NUMBER
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/632,061	RICHARD ET AL.	
	Examiner	Art Unit	
	CHRIS E. SIMMONS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-20 and 23-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-20 and 23-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 04/06/2010 have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Applicant's arguments filed 4/6/2010 regarding the failure of the references to disclose the specific elastomeric polymer, poly(methyl acrylate), have been fully considered and are persuasive. Therefore, the rejections under 3 USC 103(a) have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the prior art recognizing that poly(methyl acrylate) is an elastomeric polymer.

Claim Objections

Claim 23 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 23 depends from claim 22, which is canceled. Accordingly, claim 23 does not further limit a previous claim as required under 37 CFR 1.75(c).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 recites the limitation "said first glass transition temperature...and said second glass transition temperature" in lines 1-3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 9, 11-20, and 23-27 are rejected under 35 USC 103(a) as being unpatentable over Pinchuk et al. (US 2002/0107330) in view of Ruckenstein et al. (WO 00/59968), the combination taken further in view of Hossainy et al. (US 2001/0014717) as evidenced by Reference Polymer Properties (12/13/2009 IDS), hereinafter referred to as "RPP".

'330 discloses an intravascular or intervascular medical device (e.g., a stent; ¶ 15) comprising a therapeutic agent-releasing biocompatible block polymer (claim 5). Preferred sites for implantation or insertion of the medical device are the coronary vasculature, peripheral vasculature, esophagus, trachea, colon, gastrointestinal tract, biliary tract, urinary tract, prostate and brain (¶ 13) (claim 6).

The device may be coated with the polymeric material (¶ 11) (claim 4). By coating the device with the therapeutic agent-releasing polymeric material the therapeutic agent-releasing polymeric material is considered to read on a carrier region

that comprises said therapeutic agent (claim 2). The therapeutic agent can be precipitated onto the surface of a device or device portion. This surface can be subsequently covered with a coating of copolymer (with or without additional therapeutic agent) (¶199) (claim 3).

Said copolymer comprises a therapeutic agent (e.g., heparin; ¶ 62); heparin is an anti-thrombotic agent (claim 7).

Said polymer is a copolymer that may be linear triblock (¶ 28) or branched (¶ 32) (relevant to claims 11 and 12). Said copolymer comprises elastomeric blocks (e.g., a polyolefin such as poly(isobutylene); ¶ 33 and claim 42 and 47) and thermoplastic blocks (e.g., vinyl aromatic blocks or methacrylate blocks (¶ 8 and claim 44), especially poly(methyl methacrylate) (¶ 8, claim 45) (See abstract, ¶ 177-178) (claim 5). The elastomeric blocks are synonymous to rubbery blocks. The thermoplastic blocks of the copolymer are considered to read on a hard block of hard units (claim 1, component (b)(ii)), the species of poly(methyl methacrylate) satisfies the limitations of claims 9 and 17-19, the species of vinyl aromatic blocks satisfies the limitations of claims 9 and 15-16.

The copolymer may comprise of units that have glass transitional temperatures above 75°C (e.g., methyl methacrylate (T_g 105°C); see RPP) and below 10°C (e.g., isobutylene (T_g -73°C); see RPP), and therefore, meets the required limitations in instant claim 23. '330 does not expressly disclose graft copolymers or a rubbery block of rubbery acrylic units.

'968 discloses that great attention has been paid to graft copolymers, because of their unique molecular architecture, particular morphology, and increased number of applications. The incorporation of functional groups into the surface of polymer materials or into polymeric chains can greatly improve their properties. For instance, the direct introduction of new functionalities onto a polymer surface or the surface modification by grafting can change the surface hydrophilicity, hydrophobicity, biocompatibility, and adhesion. The direct synthesis of well-defined graft copolymers with functional groups can control not only the properties of the surface, but also the molecular parameters, architecture, and composition of the polymer. The copolymer compositions can be used to deliver drugs. The reference does not expressly teach an implantable or insertable medical device.

'717 discloses drug-delivering-coatings for implantable devices such as stents (¶ 1) and methods for forming the same (title). The device can be coated with a layer containing an acrylate polymer such as methyl acrylate (¶ 36) (claim 16) and a therapeutic agent. '717 does not expressly teach

RPP discloses the glass transition (Tg) temperature of several homopolymers, including poly(methyl acrylate) ("PMA"). The Tg for PMA is 10 degrees Celsius. This reference does not expressly teach implantable devices.

At the time of the invention it would have been obvious to a person of ordinary skill in the art to create an insertable or implantable medical device (e.g., stent) containing elastomeric and thermoplastic block copolymers as described in the '330 patent by grafting the '330 patent's copolymers as described in the '968 WIPO

document. The motivation for grafting the copolymers would have been to control not only the properties of the surface, but also the molecular parameters, architecture, and composition of the polymer as these are disclosed as being advantageous over other types of polymers as explained in the WIPO document.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended purpose. *MPEP § 2144.07.* Accordingly, it would have been obvious at the time of the invention to modify the insertable or implantable medical device containing elastomeric and thermoplastic block copolymers as described in the '330 patent by using poly(methyl acrylate) as the elastomeric polymer from '717 since it is suitable as a coating for drug-releasing implantable devices. Poly(methyl acrylate) is elastomeric and has a Tg that is lower than ambient temperature (i.e., a Tg of 10 ^{o}C) (claim 23).

Claim 27 is directed to a medical device that is sterilized. It would have been obvious to sterilize the insertable or implantable medical device of '330 in order to minimize infection. It is noted that claim 27 is directed to a product (i.e., device) made by a particular process (i.e., radiation). Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. Since it would have been obvious make a sterilized

medical device of '330, the particular sterilization process used to make the device is insufficient to make the claim patentable over the prior art.

Claim 8 is rejected under 35 USC 103(a) as being unpatentable over Pinchuk et al. (US 2002/0107330), Ruckenstein et al. (WO 00/59968) and Hossainy et al. (US 2001/0014717) as evidenced by Reference Polymer Properties (12/13/2009 IDS), the combination taken further in view of Williams (US 6,514,515).

The disclosures for Pinchuk et al., Ruckenstein et al. and Reference Polymer Properties and the rationale for their combination are outlined above. However, they do not expressly disclose an elongation at break of at least 25% at ambient temperature.

Williams relates to bioabsorbable biocompatible polymers which provide a good match between their mechanical properties and those of certain tissue structures. The bioabsorbable biocompatible polymers can be prepared with tensile strengths, elongation to breaks, and/or tensile modulus (Young's modulus) values of the tissues of the cardiovascular, gastrointestinal, kidney and genitourinary, musculoskeletal, and nervous systems, as well as those of the oral, dental, periodontal, and skin tissues. (Abstract). FIG. 1, plots the tensile strength and elongation to break values for representative FDA approved bioabsorbable biocompatible polymers against these values for different tissue structures. It displays a significant mismatch between the mechanical properties of these polymers and the different tissue structures. In

particular, it is apparent that the existing bioabsorbable biocompatible polymers are stiff, inelastic materials, with elongations to break of around 25%, yet many tissues are much more flexible, elastic, and have longer elongation to break values (above 25%). Accordingly, the biomaterial products used did not exhibit the same multi-axial physical and mechanical properties of native tissues (1st full paragraph of column 2). To remedy the problem, the inventors preferably developed polymeric devices with elongation at break above 25%. The compositions described have an advantageous ability to be sterilized by radiation (1st paragraph in column 8). The reference does not expressly teach acrylic graft copolymers.

At the time of the invention it would have been obvious to a person of ordinary skill in the art to create an insertable or implantable medical device containing graft copolymers as disclosed above having an elongation of break of at least 25% as described by Williams. The suggestion for doing so would have been to increase the flexibility and elasticity of a biomedical device to more closely match the native tissue in which the device is inserted/implanted.

Conclusion

No claims are allowed.

The following is pertinent art but has not been used for this Office action:

- 5,260,020 – disclosing irradiation as a process used to sterilize insertable devices such as catheters

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Allison M. Ford/
Primary Examiner, Art Unit 1651

/Chris E Simmons/
Examiner, Art Unit 1612